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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,313	10/31/2003	Christophe Combadiere	4239-66645	5461

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,313	COMBADIERE ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-12,18,19 and 21-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-12,18,19 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/18/05,3/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 6 to 12, 18, 19 and 21 to 27 are pending in the instant application. Claims 6, 11, 18, 21 and 22 have been amended, claims 13 to 17 and 20 have been canceled and claims 25 to 27 have been added as requested by Applicant in the correspondence filed 16 March of 2006.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 18 and 21 to 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirements. These claims encompass subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As stated in section 4 of the previous office action, the instant specification fails to describe the genus of compounds encompassed by the limitation "an agent that suppresses the H1V-1 fusion coreceptor-activitv of CCR5". Whereas the instant specification describes three different classes of proteins consisting of three specific chemokines, antibodies to an extracellular portion of CCR5, and three specific peptides corresponding to the three extracellular loops of CCR5, all of which are peptides, the instant claims encompass a process that utilizes organic compounds, inorganic

compounds or even nonmaterial entities such as heat and ionizing radiation. Yet the instant specification does not describe even a single organic or inorganic compound, nucleic acid, lipid, steroid or otherwise that has the required activity by "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.

Further, the instant specification is not enabling for the full scope of the claims because phenol, ionizing radiation or a denaturing level of heat would certainly inhibit the interaction of HIV with CCR5, as required by the instant claims, but the instant specification does not provide the guidance needed to employ such agents in the claimed process. To practice such a method would require knowledge of the route, duration and quantity of administration of that "agent" to a subject and this information is not provided by the instant specification. The text on pages 31 to 33 of the instant specification clearly fails to supply the guidance that would be needed by a routine artisan to practice the claimed method with other than the specific proteins and peptide described therein. The instant specification has also failed to disclose how these parameters are to be determined, how a similar method was practiced in the art with a different agent or to provide even a single working example, prophetic or actual, of the claimed method. In the absence of this guidance a practitioner would have to resort to a substantial amount of undue experimentation involving the variation in the amount and duration of administration of an "agent" of the instant invention and in determining a suitable route of administration. The instant situation is directly analogous to that which was addressed in *In re Colianni*, 195 U.S.P.Q. 150,(CCPA 1977), which held that a

"[d]isclosure that calls for application of "sufficient" ultrasonic energy to practice claimed method of fusing bones but does not disclose what "sufficient" dosage of ultrasonic energy might be or how those skilled in the art might select appropriate intensity, frequence, and duration, and contains no specific examples or embodiment by way of illustration of how claimed method is to be practiced does not meet requirements of 35 U.S.C. 112 first paragraph".

In so far as the instant claims encompass a process that employs a vector, there is not a single reference of record or working example provided in the instant specification of the successful administration of a therapeutic protein to a human via a nucleic acid vector. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc, v. Novo Nordisk*, 42 USPQ 2d 100,(CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure". The court further stated that "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling because one can not following the guidance presented therein and practice the disclosed method commensurate in scope with the instant claims without first making a substantial inventive contribution.

5) Claims 25 to 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1) Claim 25 is confusing because it is unclear how a chemokine can "comprise" one of the three specific chemokines recited therein.

5.2) Claims 26 and 27 are vague and indefinite because there is no antecedent basis for "the extracellular loop". Thee claims should be referring to "wherein the peptide corresponding to an extracellular loop of CCR5...".

6) Claims 6 to 12, 18, 19, 21, 23 and 24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Allaway et al. patent (6,344,545). See claim 2 of Allaway et al. Applicant urges that according to MPEP 715.05, "when the reference in question is a noncommonly owned U.S. patent or patent application publication claiming the same invention as applicant and its publication date is less then 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be by way of 37 C.F.R. 41.202 instead of 37 C.F.R. 1.131. If the reference is claiming the same invention as the application and its publication date is less than 1 year prior to the presentation of claims to that invention in the application, this fact should be noted in the Office action. The reference can then be overcome only by way of interference."

However, before an interference proceeding can be initiated, Applicant must first overcome the Allaway et al. patent under 35 U.S.C. § 102(e) by showing conception of the claimed invention prior to the 02 April, 1996 filing date of the application upon which

the Allaway et al. patent issued, thereby rendering the claims "patentable but for a judgment in the contested case" as required by 37 C.F.R. 41.102(b)(1). See M.P.E.P. 2303. This may be achieved through an affidavit or declaration under 37 CFR 1.131(a).

7) Claims 6, 9, 18, 21, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Cocchi et al. publication (SCIENCE 270:1811-1815, 15 Dec. 1995, cited by Applicant) for those reasons of record in section 7 of the previous office action. The Cocchi et al. publication expressly identified the naturally occurring chemokines RANTES, MIP-1α and MIP-1β as soluble HIV suppressive factors. The text on page 29 of the instant specification explicitly identifies RANTES, MIP-1α and MIP-1β as being encompassed by the limitation "CCR5-binding agent". Because one of ordinary skill in the art would have recognized the desirability of suppressing HIV activity in an individual infected with HIV, they would have found it *prima facie* obvious to administer RANTES, MIP-1α, and/or MIP-1β to that individual to inhibit HIV activity.

Applicant has traversed this rejection on the premise that "[t]here is no suggestion or motivation to modify the Cocchi et al. document, to arrive at the claimed invention". There certainly was. The identification by Cocchi et al. of RANTES, MIP-1α and MIP-1β as soluble HIV suppressive factors was ample motivation to administer these compounds to an individual to suppress HIV infection. The fact that RANTES, MIP-1α and MIP-1β were known to be natural products of the human body provide an artisan with more than a reasonable expectation that they would be functional in, and tolerated by, human subjects.

Applicant urges that "[s]ince there is no teaching or suggestion in Cocchi et al. that RANTES, MIP-1α, and MIP-1β are ligands of CCRS, there is no motivation in Cocchi et al. to inhibit membrane fusion between HIV and a cell that expresses CCR5 by using an agent that blocks or binds CCRS, for example by using RANTES, MIP-1α, and MIP-1β". Given that by Cocchi et al. identified RANTES, MIP-1α and MIP-1β as soluble HIV suppressive factors, one did not need to know the mode of action of these compounds to be motivated to administer them for the purpose of suppressing HIV infection. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

8) Claims 26 and 27 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9) Applicant's arguments filed 16 March of 2006 have been fully considered but they are not persuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1600